REMARKS

Claims 1-20 were previously canceled. Claims 21-31 were added by Preliminary Amendment, and now stand substantively rejected. Claims 21-26 and 28-31 are amended, and claims 32-75 are added by the present Amendment. Reconsideration of the claims is respectfully requested. The paragraph numbering below follows that of the Office Action.

Support for the amendments to claims 21 and 28-31 can be found throughout the application and at least at page 24, lines 8-11. Claims 22-26 have been amended to correct the claim dependencies. Support for new claim 32 can be found throughout the application and at least at page 6, lines 13-15. Support for new claim 33 can be found throughout the application and at least at page 7, lines 23-24. Support for new claim 34 can be found throughout the application and at least at page 7, lines 24-25. Support for new claim 35 can be found throughout the application and at least at page 8, line 4. Support for new claim 36 can be found throughout the application and at least at page 10, lines 6-12. Support for new claim 37 can be found throughout the application and at least at page 10, line 15. Support for new claim 38-44 can be found throughout the application and at least at page 11, lines 23-30. Support for new claim 45 can be found throughout the application and at least at page 21, lines 3-4. Support for new claim 46 can be found throughout the application and at least at page 24, lines 8-11. Support for new claims 47-49 can be found throughout the application and at least at page 7, lines 12-18. Support for new claim 50 can be found throughout the application and at least at page 21, lines 15-16 and Figs. 5 and 6. Support for new claims 51-54 can be found throughout the application and at least at page 21, lins 21-25 and Figs. 5 or 6. Support for new claim 55 can be found throughout the application and at least at page 22, lines 10-11. Support for new claim 56 can be found throughout the application and at least at page 22, lines 13-16 and Figs. 7 and 8. Support for new claim 57 can be found throughout the application and at least at page 22, lines 17-20 and Fig. 7. Support for new claims 58 and 59 can be found throughout the application and at least at page 22, lines 27-28 and/or Figs. 7 and 8. Support for new claim 60 can be found throughout the

application and at least at Fig. 7. Support for new claim 61 can be found throughout the application and at least at Fig. 8. Support for new claim 62 can be found throughout the application and at least at page 23, lines 3-7. Support for new claims 63-65 can be found throughout the application and at least at page 13, lines 23-27. Support for new claim 66 can be found throughout the application and at least at page 14, line 28 to page 15, line 17. Support for new claims 69-74 can be found throughout the application and at least at page 15, lines 3-4. Support for new claim 75 can be found throughout the application and at least at page 23, lines 19-21.

Rejection Under 35 U.S.C. §102

¶3. Claims 21 and 28-31 were rejected under 35 U.S.C. 102(b) as allegedly anticipated by U.S. Patent No. 5,017,372 to Hastings ["Hastings"]. This rejection is traversed in part and overcome in part as follows.

In general terms, claim 21 is drawn to a method of making a harvested mammary secretion product comprising an antibody specific for an antigen by hyperimmunizing a farm-animal for the antigen, administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal, and harvesting the mammary secretion product from the farm-animal.

As amended, the method of claim 21 recites the step of hyperimmunizing a farm-animal for the antigen via a mucosal passage of the farm-animal. Hastings fails to teach or suggest this claim element. It is well established that to anticipate a claim under §102, the reference must teach every element of the claim. Because Hastings fails to teach every element of amended claim 21, Applicant respectfully requests withdrawal of this rejection.

Similarly, amended claims 28-31 recite methods that include the step of hyperimmunizing a farm-animal for the antigen via a mucosal passage of the farm-animal. Hastings fails to teach or suggest this claim element. Because Hastings fails to teach every element of amended claims 28-31, Applicant respectfully requests withdrawal of this rejecti n.

Rejection Under 35 U.S.C. §112

¶4. Claims 22-27 were rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for depending upon canceled claims. Applicant has amended claims 22-27 to depend from pending claims. Withdrawal of this rejection is respectfully requested.

CONCLUSION

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

For the Examiner's convenient reference, attached hereto is a reproduction of the claims presently under examination, captioned **"Claims presently under examination."**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

21. (Amended) A method of making a harvested mammary secretion product comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen via a mucosal passage of the farm-animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal; and

harvesting the mammary secretion product from the farm-animal.

22. (Amended) The method of claim 21 [1], wherein the hyperimmunizing step comprises administering the antigen to an airway of the farm-animal.

23. (Amended) The method of claim 22 [2], wherein the hyperimmunizing step comprises administering the antigen intranasally to the farm-animal.

24. (Amended) The method of claim 21 [1], wherein the mammary secretion product is milk.

25. (Amended) The method of claim 21 [1], wherein the antibody is an IgA antibody.

26. (Amended) The method of claim 21 [1], further comprising boosting an immune response to the antigen in the farm-animal.

27. The method of claim 26, wherein the boosting step comprises administering the antigen to an airway, a mammary gland, and/or a supramammary lymph node of the farm-animal.

28. (Amended) A method of making an antibody composition comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen via a mucosal passage of the farm-animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal;

harvesting the mammary secretion product from the farm-animal; and

deriving the antibody composition from the harvested mammary secretion product. (page 24, lines 8-11)

29. (Amended) A method of making an antigen-specific antibody, the method comprising:

hyperimmunizing a farm-animal for an antigen via a mucosal passage of the farm-animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal;

harvesting a mammary secretion product from the farm-animal; and

deriving the antigen-specific antibody from the harvested mammary secretion product. (page 24, lines 8-11)

30. (Amended) A method of making a medicament comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen via a mucosal passage of the farm-animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal;

harvesting the mammary secretion product from the farm-animal; and

incorporating the mammary secretion product into the medicament. (page 24, lines 8-11)

31. (Amended) A method of making a food product comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen via a mucosal passage of the farm-animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal;

harvesting the mammary secretion product from the farm-animal; and

incorporating the mammary secretion product into the food product. (page 24, lines 8-11)

CLAIMS PRESENTLY UNDER EXAMINATION

21. (Amended) A method of making a harvested mammary secretion product comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen via a mucosal passage of the farm-animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal; and

harvesting the mammary secretion product from the farm-animal.

22. (Amended) The method of claim 21, wherein the hyperimmunizing step comprises administering the antigen to an airway of the farm-animal.

23. (Amended) The method of claim 22, wherein the hyperimmunizing step comprises administering the antigen intranasally to the farm-animal.

24. (Amended) The method of claim 21, wherein the mammary secretion product is milk.

25. (Amended) The method of claim 21, wherein the antibody is an IgA antibody.

26. (Amended) The method of claim 21, further comprising boosting an immune response to the antigen in the farm-animal.

27. The method of claim 26, wherein the boosting step comprises administering the antigen to an airway, a mammary gland, and/or a supramammary lymph node f the farm-animal.

28. (Amended) A method of making an antibody composition comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen via a mucosal passage of the farm-animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal;

harvesting the mammary secretion product from the farm-animal; and

deriving the antibody composition from the harvested mammary secretion product.

29. (Amended) A method of making an antigen-specific antibody, the method comprising:

hyperimmunizing a farm-animal for an antigen via a mucosal passage of the farm-animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal;

harvesting a mammary secretion product from the farm-animal; and

deriving the antigen-specific antibody from the harvested mammary secretion product.

30. (Amended) A method of making a medicament comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen via a mucosal passage of the farm-animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal;

harvesting the mammary secretion product from the farm-animal; and

incorporating the mammary secretion product into the medicament.

31. (Amended) A method of making a food product comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen via a mucosal passage of the farm-animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal;

harvesting the mammary secretion product from the farm-animal; and

incorporating the mammary secretion product into the food product.

32. (New) The method of claim 21, wherein the antigen is administered through administering nucleic acid encoding the antigen or functional equivalent thereof.

33. (New) The method of claim 21, wherein the antigen is administered at least once in the supramammary lymph node.

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34. (New) The method of claim 21, wherein the antigen is administered at least twice in the supramammary lymph node.

35. (New) The method of claim 21, wherein the farm-animal is a cow or a goat.

36. (New) The method of claim 21, wherein the hyperimmunizing step further comprises administering an adjuvant to the farm-animal.

37. (New) The method of claim 36, wherein the adjuvant is toxin B of *Clostridium difficile*.

38. (New) The method of claim 21, wherein the antigen is derived from a culture of *Clostridium difficile*.

39. (New) The method of claim 38, wherein the antigen is a protein from a *Clostridium difficile* (VPI10463) cell.

40. (New) The method of claim 38, wherein the antigen is a *Clostridium difficile* spore.

41. (New) The method of claim 38, wherein the antigen comprises *Clostridium difficile* Toxin A.

42. (New) The method of claim 38, wherein the antigen comprises *Clostridium difficile* Toxin B.

43. (New) The method of claim 38, wherein the antibody is specific for a protein of *Clostridium difficile.*

44. (New) The method of claim 38, wherein the antibody is specific for a *Clostridium difficile* spore.

45. (New) The method of claim 21, wherein the farm-animal is a lactating farm-animal.

46. (New) The method of claim 21, wherein the hyperimmunizing step comprises administering the antigen via an intramucosal route selected from the group consisting of intraudder, intravaginal, intrarectal, or intranasal.

47. (New) The method of claim 21, wherein the airway administration is achieved in the form of aerosols.

48. (New) The method of claim 21, wherein the hyperimmunizing step comprises at least two airway administrations of the antigen.

49. (New) The method of claim 21, wherein the hyperimmunizing step comprises at least four airway administrations of the antigen.

50. (New) The method of claim 21, wherein the antigen is administered to the mammary gland and/or supramammary lymph node of the farm-animal about 6 weeks following the hyperimmunizing step.

51. (New) The method of claim 21, wherein the harvested mammary secretion product has an IgA titer of at least 1000 units/ml.

52. (New) The method of claim 21, wherein the harvested mammary secretion product has an IgA titer of at least 1000 units/ml and is harvested up to about 10 weeks after the antigen is administered to the mammary gland and/or the supramammary lymph node of the farm-animal.

53. (New) The method of claim 21, wherein the harvested mammary secretion product has an IgG titer of at least 100 units/ml.

54. (New) The method of claim 21, wherein the harvested mammary secretion product has an IgG titer of at least 100 units/ml and is harvested up to about 8 weeks after the antigen is administered to the mammary gland and/or the supramammary lymph node of the farm-animal.

55. (New) The method of claim 21, wherein the hyperimmunizing step further comprises administering the antigen intramuscularly to the farm animal.

56. (New) The method of claim 21, wherein the antigen is administered to the mammary gland and/or supramammary lymph node of the farm-animal about 3 weeks following the hyperimmunizing step.

57. (New) The method of claim 21, wherein the harvested mammary secretion product has an IgG titer of about 130 units/ml to about 430 units/ml.

58. (New) The method of claim 21, wherein a second hyperimmunization step is performed after the antigen is administered to the mammary gland and/or supramammary lymph node of the farm-animal.

59. (New) The method of claim 58, wherein the antigen is administered a second time to the mammary gland and/or supramammary lymph node of the farm-animal following the second hyperimmunization step.

60. (New) The method of claim 59, wherein the mammary secretion product harvested after the second mammary gland and/or supramammary lymph node administration has an IgG titer of at least 400 units/ml.

61. (New) The method of claim 59, wherein the mammary secretion product harvested after the second mammary gland and/or supramammary lymph node administration has an IgA titer of at least 3500 units/ml.

62. (New) The method of claim 59, wherein the mammary secretion product harvested after the second mammary gland and/or supramammary lymph node administration does not have a strong quarter specificity for IgA titer.

63. (New) The method of claim 24, wherein the milk from the farm-animal comprises at least 0.5 μg/ml of antibody specific for the antigen.

64. (New) The method of claim 24, wherein the milk from the farm-animal comprises at least 15 μg/ml of antibody specific for the antigen.

65. (New) The method of claim 24, wherein the milk from the farm-animal comprises at least 50 μg/ml of antibody specific for the antigen.

66. (New) The method of claim 24, wherein the milk from the farm-animal comprises the antibody specific for the antigen in a quantity of at least 50 percent of the average quantity of the antibody specific for the antigen that is obtainable from a colostrum of the farm-animal.

67. (New) The method of claim 24, wherein the milk from the farm-animal comprises the antibody specific for the antigen in a quantity of at least 100 percent of the average quantity of the antibody specific for the antigen that is obtainable from a colostrum of the farm-animal.

68. (New) The method of claim 24, wherein the milk from the farm-animal comprises the antibody specific for the antigen in a quantity of at least 200 percent of the average quantity of the antibody specific for the antigen that is obtainable from a colostrum of the farm-animal.

69. (New) The method of claim 62, wherein the antibody specific for the antigen is an IgA antibody.

70. (New) The method of claim 63, wherein the antibody specific for the antigen is an IgA antibody.

71. (New) The method of claim 64, wherein the antibody specific for the antigen is an IgA antibody.

72. (New) The method of claim 65, wherein the antibody specific for the antigen is an IgA antibody.

73. (New) The method of claim 66, wherein the antibody specific for the antigen is an IgA antibody.

74. (New) The method of claim 67, wherein the antibody specific for the antigen is an IgA antibody.

75. (New) A method of making a harvested mammary secretion product comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen;

administering the antigen to a supramammary lymph node of the farm-animal; and

harvesting the mammary secretion product from the farm-animal.